PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Masao MORI et al. Group Art Unit: 4161

Application No.: 10/557,922 Examiner: P. ZAREK

Filed: December 22, 2005 Docket No.: 126068

For: COMPOUNDS AND PREPARATIONS HAVING ANTIVIRAL EFFECT

RESPONSE TO RESTRICTION AND ELECTION OF SPECIES REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the August 12, 2008 Restriction/Election of Species Requirement, Applicants provisionally elect Group I, claims 1-5 and 7-14, with traverse.

Applicants also provisionally elect the Species of Compound 6a in Fig. 3, wherein (1) R_1 is $-(CH_2)_fCH_3$, and f is 0 (i.e., R_1 is CH_3); (2) R_2 is $-CO(CH_2)_nCH_3$, and n is 8; and (3) R_3, R_4 and R_5 are H; with traverse. Applicants submit that claims 1 and 5-14 read on the elected species and that at least claims 1 and 6-14 are generic.

National stage applications filed under 35 U.S.C. §371 are subject to unity of invention practice as set forth in PCT Rule 13, and are not subject to U.S. restriction practice. *See* MPEP §1893.03(d). PCT Rule 13.1 provides that an "international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept." PCT Rule 13.2 states:

> Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a

> technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

A lack of unity of invention may be apparent "*a priori*," that is, before considering the claims in relation to any prior art, or may only become apparent "*a posteriori*," that is, after taking the prior art into consideration. *See* MPEP §1850(II), quoting *International Search and Preliminary Examination Guidelines* ("ISPE") 10.03. Lack of *a priori* unity of invention only exists if there is no subject matter common to all claims. *Id.* If *a priori* unity of invention exists between the claims, or, in other words, if there is subject matter common to all the claims, a lack of unity of invention may only be established *a posteriori* by showing that the common subject matter does not define a contribution over the prior art. *Id.*

Furthermore, unity of invention only needs to be determined in the first place between independent claims, and not the dependent claims, as stated in ISPE 10.06:

> Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of one or more other claims and contains a reference, preferably at the beginning, to the other claim or claims and then states the additional features claimed (Rule 6.4).

See also MPEP §1850(II). ISPE 10.07 further provides:

> If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention.

See also MPEP §1850(II).

Claim 1 is directed to an antiviral preparation characterized by comprising as an active ingredient, at least a phorbol derivative of formula 1. Claims 2-14 depend from claim 1.

Accordingly, all the claims share common subject matter and, therefore, *a priori* unity of invention exists between all the claims. Thus, for the present application, a lack of unity of invention may only be determined *a posteriori*, or in other words, after a search of the prior art has been conducted and it is established that all the elements of the independent claim are known. *See* ISPE 10.07 and 10.08.

The Office Action does not establish that each and every element of the subject matter of independent claim 1 is known in the prior art. Namely, the Office Action does not establish that the prior art discloses a phorbol derivative of claim 1. The Office Action asserts that U.S. Patent No. 6,268,395 discloses a phorbol derivative of formula 1, wherein R_1, R_3, R_4 and R_5 are H and R_2 is $-COCH_3$, which the Office Action asserts reads on the phorbol derivative of claim 1. See Office Action page 2. However, claim 1 recites, "An antiviral preparation characterized by comprising as an active ingredient, at least a phorbol derivative of formula 1 ... wherein R_1 is a group of $-(CH_2)_aX(CH_2)_bCH_3$ wherein X is O or S, a is a number of 1 to 3, and b is a number of 0 to 5, a group of $-(CH_2)_cX(CH_2)_dYCH_3$ wherein X and Y are O or S, c is a number of 1 to 3, and d is a number of 1 to 5, a group of $-CO(CH_2)_eCH_3$ wherein e is a number of 0 to 12, or a group of $-(CH_2)_fCH_3$ wherein f is a number of 0 to 5, R_2 is a group of $-CO(CH_2)_nCH_3$ wherein n is a number of 3 to 12." Nowhere does claim 1 recite that R_1 can be H or that R_2 can be $-COCH_3$. Therefore, Applicants respectfully submit that lack of unity of invention has not been established, and thus a restriction requirement based on a lack of unity of invention is improper.

Moreover, the Office Action has applied the incorrect standard in requiring an election between species. Although unity of invention practice under PCT Rule 13 recognizes that alternate forms of an invention may be present in separate independent claims, or in a single claim, restriction between distinct embodiments of a single claim may only be required if

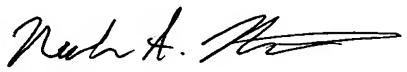
there is a lack of unity of invention in that claim, or, in other words, the distinct embodiments share no common subject matter that defines a contribution over the prior art. *See* ISPE 10.09; MPEP §1850(II). The "patentably distinct species" standard, as applied under U.S. restriction practice, is not applicable to the current claims. Furthermore, the Office Action fails to establish that the "patentably distinct species" lack *a posteriori* unity of invention. Accordingly, the election of species requirement is improper and must be withdrawn.

It is also respectfully submitted that the subject matter of all claims and species are sufficiently related that a thorough search for the subject matter of any one Group of claims or Group of species would encompass a search for the subject matter of the remaining claims and species. Thus, it is respectfully submitted that the search and examination of the entire application could be made without serious burden. See MPEP §803 in which it is stated that "if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions" (emphasis added). It is respectfully submitted that this policy should apply in the present application in order to avoid unnecessary delay and expense to Applicants and duplicative examination by the Patent Office.

Applicants further understand, however, that upon search, examination and allowance of the elected species, search and examination will continue as to the non-elected species within the scope of the generic claims.

Thus, withdrawal of the Restriction and Election of Species Requirement is respectfully requested.

Respectfully submitted,



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